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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,994	03/03/2004	Alberto Orfao De Matos Correia E Valle	DE MATOS CORREIA E VALLE	4880
25889	7590	05/14/2008		
COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER GABEL, GAILENE	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 05/14/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/791,994

Applicant(s)

DE MATOS CORREIA E VALLE ET AL.

Examiner

GAILENE R. GABEL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)</p> <p> Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)</p> <p> Paper No(s)/Mail Date _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
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DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed January 14, 2008, is acknowledged and has been entered. Claims 1 has been amended. Currently, claims 1-22 and 25-34 are pending and are under examination.

Withdrawn Rejections or Objections

2. All rejections or objections not reiterated herein, have been withdrawn.

Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-22 and 25-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for obtaining at least two light scatter measurements and at least four fluorescence intensity measurements of each stained cell in each of the samples and each of the microparticles in order to provide identification of aberrant phenotypes expressed by neoplastic cells, does not reasonably provide enablement for obtaining a [single] light scatter fluorescence emission measurements of each stained cell in each of the normal/reactive and neoplastic samples. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As set forth in *In re Wands*, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

With respect to the measurements obtained from each stained cell and microbead in the samples, the claimed method recites sequential measurement of only fluorescence emissions associated to large numbers of cells stained with each of the combinations of monoclonal antibodies from the normal/reactive samples and neoplastic sample, without any limitation as to the number of fluorescence emissions measurements are performed for each cell. Page 13, second full paragraph of the specification; however, provides that for each stained cell in the samples and microparticle, at least two measures of light scatter and at least four measures of fluorescence emissions are required to be taken, sequentially measured per sample aliquot, stored into two independent list mode data files, merged into a new data file whereupon phenotypic aberrations are established, identified, and defined, in order for the method to work. In page 18, first full paragraph of the specification, it is stated that it is by quantifying the amount of measurements of light scatters and fluorescence emissions for each individual population of neoplastic cells as compared to those populations of normal cells stained with identical panels, that statistical information on the most discriminant aberrant phenotypes displayed by the neoplastic cells can be derived. Each aberrant

phenotype may be composed of a combination of two or more light scatter and fluorescence measurements. The breadth of the claims encompass only using measurement of a light scatter and a fluorescence emission by stained cells; without specifically stating how phenotypic aberrations can be established and defined without undue experimentation, absent specific recitation of required at least two light scatter measurements and at least four fluorescence intensity measurements, which is commensurate in scope with Applicant's disclosure.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Response to Arguments

4. Applicant's arguments filed January 14, 2008 have been fully considered but they are not persuasive.

Applicant amends step b) of claim 1 to recite, "sequentially measuring light scatter and fluorescence emissions" and then contends that such amendment obviates the enablement rejection.

In response, Applicant's argument is not persuasive because the amendment cannot be deemed to obviate the enablement rejection. Specifically, Applicant's argument and disclosure at page 13 of the specification is not commensurate in scope with the claimed invention, because claim 1, as amended, recites "sequentially measuring light scatter and fluorescence emissions associated to large number of cells..."; however, page 13 of Applicant's disclosure provides that at least two measures of light scatter and at least four measures of fluorescence intensity are required and taken for each of the microparticles and stained cells in the sample in order to perform identification of aberrant phenotypes expressed by the

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neoplastic cells. Accordingly, claims 1-22 and 25-34 are not enabled for the scope of invention recited in the rejected claims.

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

May 8, 2008